

Serial No.: 10/801,231
Examiner: Michael Thaler
Group Art Unit: 3731

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STATUS OF THE CLAIMS

Claims 1-29 are pending herein, claims 1 and 21 being the independent claims.

Claims 24-29 have been withdrawn pursuant to a restriction requirement. Applicants hereby amend claims 1, 6, 7, 9-16, and 18-21. Support for the amendment to claims 1, 6, 7, 9-16, and 18-21 is provided, *inter alia*, in paragraphs [0003], [0004] and [0037] of the specification. Applicants state that there is no issue of new matter.

Rejection under 35 U.S.C. §102(b) or §103(a) – Sawhney et al.

Claims 1, 2, 5, 6, 11-16 and 18-23 are rejected under 35 U.S.C. 102(b) as anticipated by or, or in the alternative, under 35 U.S.C. 103(a) as obvious over Sawhney et al. (U.S. Patent No. 6,379,373). Claims 3, 4, 7-10, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney et al.

In response, Applicants respectfully traverse the rejections over Sawhney et al. Applicants submit that the invention is neither anticipated by nor rendered unpatentable in light of the disclosures of Sawhney et al. As amended, independent claims 1 and 21, from which the remainder of the rejected claims depend, are directed to the following (emphasis added):

1. A method of providing a solid polymeric body within a subject, said method comprising:
 injecting a fluid comprising a crosslinkable polymer into a container that is positioned within the subject;
 crosslinking said crosslinkable polymer in said container, thereby forming a crosslinked solid polymeric body in the container; and
 releasing said crosslinked solid polymeric body into said subject.

21. A method of providing a solid polymeric body within a subject, said method comprising: (a) injecting a first fluid comprising a first polymer into a container that is positioned within the subject, (b) injecting a second fluid comprising a second, crosslinkable polymer into said container, said second fluid having a lower viscosity than said first fluid; (c) *crosslinking said crosslinkable polymer in said container, thereby forming a crosslinked solid polymeric body in said container; and (d) releasing said crosslinked solid polymeric body into said subject.*

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The Sawhney et al. reference fails as an anticipatory reference because it fails to teach all of the claimed features of independent claims 1 and 21, as amended. For a reference to anticipate a claim it *must disclose each and every element of the claim*. See MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

Specifically, Sawhney et al. simply does not teach or suggest the following claim features that are found in both independent claims 1 and 21, either explicitly or inherently:

- (1) *crosslinking said crosslinkable polymer in said container, thereby forming a crosslinked solid polymeric body in the container, and*
- (2) *releasing said crosslinked solid polymeric body into said subject.*

Instead, Sawhney et al. teaches a method for forming "*hydrogels*" via the following:

- (1) *"begin crosslinking in chamber 46," thereby forming a "partially-formed gel" in the chamber 46, and*
- (2) *"extrud[ing] said "partially-formed gel" through outlet ports 47 and into the lumen or void."*

(Sawhney et al., col. 9, line 64 to col. 10, line 9).

The significance of these differences in the claim features becomes very apparent when one considers the divergent goals and problems to be solved by the method of Sawhney et al. versus those of the present invention. As taught by Applicants in the specification, the present invention solves the problems inherent in prior art techniques such as that of Sawhney et al., wherein "crosslinked material is extruded from an outlet port of a container, which extrusion process would clearly result in a *radical change in three-dimensional shape of the crosslinked material* (e.g., with the material undergoing extreme deformation or flow), as it is *forced* from the container." (paragraph [0023])(emphasis added). This problem is solved by Applicants, for example, by crosslinking the crosslinkable material until a *solid is formed in the container*. Sawhney et al., in contrast, is concerned with "reduce[ing] the risk that the prepolymer solutions [used to form the hydrogel] will cause embolization in other portions of, for example, the vascular system. To reduce this risk, Sawhney et al. proposes creating some physical crosslinks in a mixing chamber 46 and after placing in a lumen or void, creating chemical crosslinks. The

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physical crosslinks create "sufficient mechanical integrity [in the gel] to remain in position in the body lumen or void during the chemical crosslinking process." (Sawhney et al., col. 10, lines 16-20). Thus, remainder of the crosslinking (i.e. chemical crosslinking) occurs after the gel is extruded and positioned in the lumen or void.

In addition, the Examiner argues that the "partial crosslinking" taught in Sawhney et al. anticipates the "crosslinking" feature of the claims (see page 3 of the Office Action which states "crosslinking (i.e. partially crosslinking)"). However, Applicants respectfully point out that Applicants' invention claims "crosslinking to form a solid in the container," and Sawhney et al. does not teach such an step. Even more importantly, forming a solid in the container would defeat the stated purpose of Sawhney et al., which is to form enough "physical crosslinks" by mixing prepolymer solutions within the mixing chamber to create a "partially-formed gel" that has "sufficient mechanical integrity to remain in position in the body lumen or void during the chemical crosslinking process." However, the partially-formed gel can still be easily "extruded from mixing chamber 46 through outlet ports 47." Applicants assert that one of ordinary skill in the art would appreciate that Sawhney et al. does not teach forming a solid in the container precisely because such solidification would make it difficult to "extrude" the solid through the outlet ports 47 and into the lumen or void."

Since Sawhney et al. fails as an anticipatory reference, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection over Sawhney et al. Claims 2, 5, 6, 11-16, and 18-20 and 22-23 depend directly on claims 18 or 21 and contain additional distinguishing features. The rejection of those claims fails at least because of the fundamental defect discussed above with respect to independent claims 1 and 21.

The Examiner has also rejected the claims stating that they are obvious in light of the disclosures of Sawhney et al.

In response, Applicants respectfully state that the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation

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of success. *Finally, the prior art reference (or references when combined) must teach or suggest all the claimed features.* MPEP § 2142-2143; see *In re Jones*, 958 F.2d 347, 351, 21 U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992); *In re Fine*, 837 F.2d 1071, 1075, 5 U.S.P.Q. 1596, 1598-99 (Fed. Cir. 1988).

As detailed above with respect to the anticipatory rejection of the same claims, Sawhney et al. fails to teach at least two elements of the methods of independent claims 1 and 21, upon which all the remainder of the rejected claims depend. The Examiner has cited no additional evidence or reference to remedy this deficiency. Rather, particularly with respect to certain claim elements in rejected claims 3, 4, 7-10 and 17, the Examiner asserts that various features are "old and well known in this art" without providing any rationale or presenting any evidence in support of his conclusion. Applicants respectfully state that even if we were to agree that those features are indeed "old and well known," which they are not, such teachings still fail to teach or suggest the following elements of the independent claims:

crosslinking said crosslinkable polymer in said container, thereby forming a crosslinked solid polymeric body in the container;

releasing said crosslinked solid polymeric body into said subject.

Given such deficiency in the cited art, Applicants respectfully state that the burden of establishing a *prima facie* of obviousness has not been met and requests that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. 103(a).

CONCLUSION

In view of the above, Applicant submits that all pending claims are in condition for allowance. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

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FEEs

All fees due and owing in respect to this Amendment may be charged to deposit account number 50-1047.

Respectfully submitted,

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